

Europäisches Patentamt

European Patent Office

Office européen des brevets



EP 0 861 672 A1

(12)

EUROPEAN PATENT APPLICATION

published in accordance with Art. 158(3) EPC

(43) Date of publication: 02.09.1998 Bulletin 1998/36

(21) Application number: 96933687.4

(22) Date of filing: 19.09.1996

(51) Int. Cl.⁶: **A61M 16/12**

(11)

(86) International application number: PCT/RU96/00270

(87) International publication number: WO 97/10869 (27.03.1997 Gazette 1997/14)

(84) Designated Contracting States:

AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC

NL PT SE

(30) Priority: 20.09.1995 RU 95116346

(71) Applicant:
Panina, Elena Vladimirovna
Moscow, 103104 (RU)

(72) Inventors:

- PAVLOV, Boris Nikolaevich Moscow, 113545 (RU)
- LOGUNOV, Alexei Timofeevich Moskovskaya obl., 141700 (RU)

- SMIRNOV, Igor Alexeevich Moscow, 123480 (RU)
- BARANOV, Viktor Michailovich Moscow, 123182 (RU)
- LASTOCHKIN, Georgy Ivanovich Leningradskaya obl., 189150 (RU)
- KOTOV, Alexandr Nikolaevich Moscow, 125057 (RU)
- (74) Representative:
 Jehan, Robert et al
 Williams, Powell & Associates,
 4 St Paul's Churchyard
 London EC4M 8AY (GB)

(54) METHOD OF PRODUCING A BREATHING MIXTURE AND AN APPARATUS FOR APPLYING THE METHOD

(57) The invention relates to medicine and means of medical engineering and can find application in medical practice for treating a number of diseases with the aid of breathing gas mixtures, including affections resulting from emergency situations.

The essence of the invention consists in that a gas mixture is fed in a circulatory flow at a volume rate of flow from 3 to 120 l/min, involving cleaning of the mixture and adjusting its temperature and qualitative and quantitative composition which contains oxygen and at least one of the following gases (with a maximum 95% percent content of each gas): helium, and/or argon, and/or neon, and/or crypton, and/or xenon, and/or radon, and/or nitrogen, and/or nitrogen monoxide, and/or sulfur hexafluoride, or a mixture thereof; the breathing mixture may be doped with medicinal agents; the carbon-dioxide content of the inhaled air is adjustable using the exhaled carbon dioxide; an apparatus for forming a breathing gas mixture is provided with a circulation circuit built up by the breathing bag, a gas flow inducer, a temperature controller, and at least one absorbent filter of carbon dioxide, moisture, and harmful microimpurities exhaled by the patient; the circulation circuit communicates with an oxygen gas analyzer and is further provided with a carbon-dioxide gas analyzer

together with the oxygen analyzer, a measuring unit electrically connected to the control unit, and the breathing mask is connected, through pipings provided with valves, to the circulation circuit.

Description

Technical Field

The invention relates to medicine and means of medical engineering; it can find application in treating a number of diseases with the aid of breathing gas mixtures, including affections resulting from emergency situations.

Background Art

One prior-art method for producing a gas mixture for intermittent normobaric hypoxia is known to comprise depleting atmospheric air of oxygen by compressing it in a compressor up to 0.3 to 1.5 MPa and passing the thus-compressed air through a polymer membrane made of hollow fibres, followed by feeding the resultant mixture to the patient through a flow rate meter, a humidifier, and a mask provided with a breathing valve, and a device for carrying said method into effect, comprising a breathing bag, a mask with a breathing valve, to which mask the prepared gas mixture is fed along pipings, a compressor, a polymer membrane, a humidifier, a flow rate meter, and a gas analyzer (RU 2,004,261, A2 1994, IPC A61M 16/00).

The closest to the method proposed in the present invention is the method for forming a breathing gas mixture by mixing compressed gases fed along a piping, followed by controlled feeding of said gas mixture to the breathing mask, and an apparatus which realizes said method, comprising a device for producing a gas mixture, having a source of compressed gas, said source communicating therewith through a gas mixture composition regulator and a flow rate meter, a breathing bag, a breathing mask with an inhalation valve and an exhalation valve, an oxygen gas analyzer, and a control unit (SU 1,793,934, A2, 1993, A61M 16/00).

However, field of application of said known methods, apparatus, and devices in medical practice is limited due to an insufficient therapeutic efficacy stemming from the fact that they use an atmospheric air (nitrogenoxygen) mixture as the breathing mixture.

Disclosure of the Invention

The present invention has for its principal object to extend the functional capabilities and increase the efficiency of treatment by modifying a qualitative composition of inhaled gas mixtures, as well as to reduce the consumption of gases constituting said mixtures.

The foregoing object is accomplished in a method for forming a breathing gas mixture, comprising feeding said mixture in a circulatory flow at a volume rate of flow from 3 to 120 l/min and cleaning it of carbon dioxide, moisture, and harmful microimpurities; the temperature of the gas mixture when inhaled is controlled in a range of from minus 10 to plus 130°C; there are also fed to

said mask binary and multicomponent gas mixtures of the various qualitative and quantitative composition, said gas mixtures containing oxygen and at least one of the following gases (with a maximum 95% percent content of each gas in the mixture involved): helium, and/or argon, and/or neon, and/or crypton, and/or xenon, and/or radon, and/or nitrogen, and/or nitrogen monoxide, and/or sulfur hexafluoride, or a mixture thereof; the breathing mixture may be doped with medicinal agents; the carbon-dioxide content of the inhaled air may be adjusted in a range from 0.0001 to 5%, using the exhaled carbon dioxide for the purpose; inhalation resistance may be reduced by admitting an excess pressure; the carbon-dioxide absorption conditions may be improved by increasing the rate of gas mixture flow through a sorbent bed, and the carbon-dioxide content of the inhaled gas mixture may be adjusted by bifurcating the exhaled gas mixture flow into two streams one of which is admitted to pass through the sorbent bed, while the other stream bypasses the latter.

The foregoing object is also accomplished in an apparatus for forming a breaching gas mixture, comprising a device for producing a gas mixture, said device appearing as a number of containers holding compressed oxygen and also at least one of the following gases: helium, and/or argon, and/or neon, and/or crypton, and/or xenon, and/or radon, and/or nitrogen, and/or nitrogen monoxide, and/or sulfur hexafluoride, or a mixture thereof, said containers communicating with a breathing bag through pipings provided with stop valves, at least the compressed oxygen container being provided with a valve remote-controlled from the control unit; the apparatus is provided with a circulation circuit built up by the breathing bag, a gas flow inducer, a temperature controller, and at least one absorbent filter of carbon dioxide, moisture, and harmful microimpurities exhaled by the patient into the apparatus, all these intercommunicating through pipings; said circulation circuit communicates with an oxygen gas analyzer and is additionally provided with a carbon-dioxide gas analyzer and a temperature gauge, both of which establish, together with said oxygen analyzer, a measuring unit electrically connected to the control unit, and the mask is connected, through pipings with valves, to said circulation circuit; an inhaler may be interposed between the inhalation valve and the mask and be connected to the piping that feeds the gas mixture to the mask, said inhaler being aimed at feeding medicinal agents or moisture; the carbon-dioxide absorbent filter may be by-passed by an additional piping provided with stop valves and aimed at feeding part of a carbon dioxide-enriched gas flow directly to the breathing bag, thus by-passing said carbon-dioxide absorbent filter; an exhalation piping may be provided with a gas flow switch in order that the apparatus may operate on an open cycle; the sorbent may be revivifiable and be provided with a thermal reactivator; the apparatus may further comprise a device for cleaning gases of microflora, said device being cut into

the gas-mixture exhalation piping; the circulation circuit may comprise a non-return valve preventing reversal of the gas flow; the apparatus may further comprise a device for determining patient's basal metabolism against his/her breathing, and the breathing bag may be provided with a relief valve with an adjustable pressure setting.

The herein-proposed method for producing a breathing gas mixture contemplates use of rather costly gases, especially helium, whereas performing circulation jointly with regeneration of a predetermined mixture with the aid of the proposed apparatus is most economic and efficient as minimizing loss of the gases used.

Practical utilization of the present invention enables one to obtain a technical effect consisting in that use of gases having properties other than air has contributes to a high therapeutic effect, while feeding gases in a circulation flow and their regeneration allows of using the gas mixture both efficiently and economically, and the use of the invention becomes more efficient due to the fact that the temperature of the breathing mixture is controlled and inhalation of medicinal agents is provided.

Furthermore, a possibility of using a variety of gases in the breathing mixture allows of rendering medical aid to patients who sustained overcooling, this being due to extrahigh heat conductivity of helium. On the other hand, use of, e.g., nitrogen monoxide enables one to relieve pain in wounded patients, as well as to use the apparatus as the anesthesia apparatus in surgery.

Brief Description of the Accompanying Drawings

In what follows the present invention is illustrated in the accompanying drawing, presenting a functional diagram of the apparatus for forming a breathing mixture, whereby the herein-proposed method is carried into effect.

Best Method of Carrying Out the Invention

The apparatus comprises a device for forming a gas mixture, said device appearing as a container 1 holding compressed oxygen (O2) and provided with a control valve 2, as well as at least one container 3 provided with a control valve 4 and holding one of the following gases: helium (He), nitrogen monoxide (N20), sulfur hexafluoride (SF6), as well as other gases (namely, Rn, Xe, Kr, Ar, Ne, N2) or mixtures thereof. The containers 1 and 3 communicate with a breathing bag 5 through pipings 6. The container 1 holding O2 has a controllable valve 7 connected to a control unit 8. The apparatus further comprises a gas flow inducer 9, a temperature controller 10, absorbent filters 11 and 12 of carbon dioxide, and moisture and harmful impurities, respectively, exhaled by the patient into the apparatus, said absorbent filters communicating to each other and

to the breathing bag through a piping so as to establish a closed circulation circuit, which is also provided with an oxygen gas analyzer 14 and a carbon-dioxide gas analyzer 15, and a temperature gauge 16, all of these forming a unit for measuring the gas mixture parameters, electrically connected to the control unit 8. A mask 19 is connected to the circulation circuit along a piping 20 and through an inhalation valve 17 and an exhalation valve 18. An inhaler 21 connected to the control unit 8 may be cut into the piping 20 between the inhalation valve 17 and the mask 20 for feeding medicinal agents or moisture. The carbon-dioxide absorbent filter 11 may be provided with a by-pass piping 22 having a controllable valve 23 connected to the control unit 8 for feeding part of a carbon dioxide-enriched gas flow directly to the breathing bag 5, thus by-passing the absorbent filter 11. A gas flow switch 24 may be provided in the exhalation line of the circulation circuit in order that the apparatus may operate on an open cycle, as well as a device 25 for cleaning gases of microflora. The circulation circuit of the apparatus may further comprise a non-return valve 26 aimed at providing a required direction of the gas flow in the circulation circuit (i.e., through the absorbent filters 12 and 11) and preventing filling the breathing bag 5 with an unfiltered gas mixture, that is, preventing reversal of the gas flow.

The breathing bag 5 may further comprise a relief valve 27 with an adjustable pressure setting, which protects the breathing bag against bursting with compressed gases by appropriately adjusting the bag interior pressure.

The absorbent filter 11 may be revivifiable and be provided, e.g., with a thermal reactivator.

Carbon dioxide is absorbed when a humid gas mixture passes through the absorbent filter 11, according to the following reaction:

Heating the absorbent filter 11 to 220-240°C results in that the reverse reaction proceeds:

$$2KHCO3 \rightarrow KHCO3 + CO2 + H2O$$
,

which is accompanied by releasing carbon-dioxide gas and moisture into the surrounding atmosphere, as well as by restoring the absorptive capacity of the sorbent, whereby the thermally reactivated a 11 can be reused many times.

In the alternative embodiments of the proposed apparatus use may be made of a sorbent having some other chemical composition, (solid, such as zeolites, or liquid, such as amines) buy being obligatorily a revivifiable one.

It is due to extremely high fluidity and thermal conductivity of helium that favorable conditions are provided for heating human organism, as well as for facilitating pulmonary ventilation. Moreover, while varying the oxy20

45

55

gen content of the breathing mixture treatment under conditions of hyperoxia, normoxia, and hypoxia can be performed.

The flow inducer 9 is instrumental, whenever necessary, in reducing gasodynamic inhalation resistance 5 by admitting an excess pressure, which is especially important in case of a severe patient's condition accompanied by stertorous respiration.

Provision is also made in the proposed apparatus for establishing hypercapnic conditions due to a controlled bifurcating of the exhaled gas flow into two parts, one of which is directed to the carbon-dioxide absorbent filter 11, while the other bypasses said filter. Whenever the whole gas flow passes through the carbon-dioxide absorbent filter 11, the carbon-dioxide concentration in the inspired air approximates zero. In addition, a possibility is provided of administering pharmaceuticals which can be fed through the inhaler 21 to the piping 20 between the inhalation valve 17 and the mask 19.

The exhaled air enriched with carbon dioxide, moisture, harmful impurities, and microflora first is passed through the device 25 for cleaning air of microflora, and then is fed through the exhalation valve 18 to the carbon-dioxide absorbent filter 11 which is provided with a bypass pipeline having the controllable valve for adjust- 25 ing the carbon-dioxide content of the inhaled air in a range from 0.0001 to 5%, whereupon the gas mixture is fed, through the breathing bag 5 and the flow inducer 9, to the oxygen gas analyzer 14. Use of such gas mixtures (with an increased carbon-dioxide content, the socalled hypercapnic mixtures) permits, e.g., improving oxygen supply of cerebral blood vessels.

Owing to the fact that helium is in substantially inassimilable in human organism and oxygen consumption rate is within 7 and 200 l/min (depending on physical load, general state of organism, and other factors), the oxygen gas analyzer 14 may indicate that the O2 content of the gas mixture is below the preset value. As a result, a signal is delivered through the control unit 8 to the controllable valve 7 to open for a metered oxygen 40 supply to the circulation circuit. Once the oxygen concentration therein has reached the preset value, the controllable valve 7 is closed. The volume rate of the gas mixture flow along a closed circuit is from 3 to 120 I/min in accordance with patient's demand.

Industrial Applicability

The invention can find application in medical practice in treating a number of diseases and in rendering an 50 efficient medical aid to patients, victims of emergency situations, and sufferers of home accidents.

Claims

1. A method for forming a breathing gas mixture by mixing compressed gases, followed by controlled feeding of the resultant gas mixture to a breathing

mask, CHARACTERIZED in that said mixture is fed in a circulatory flow at a volume rate of flow from 3 to 120 I/min and cleaning it of carbon dioxide, moisture, and harmful microimpurities; the temperature of said gas mixture when inhaled is controlled in a range of from minus 10 to plus 130°C; there are also fed to said mask binary and multicomponent gas mixtures with the controlled qualitative and quantitative composition, said gas mixtures containing oxygen and at least one of the following gases (with a maximum 95% percent content of each gas in the mixture involved: helium, and/or argon, and/or neon, and/or crypton, and/or xenon, and/or radon, and/or nitrogen, and/or nitrogen monoxide, and/or sulfur hexafluoride, or a mixture thereof.

- 2. A method as set forth in claim 1, CHARACTER-IZED in that medical agents are added to the breathing mixture.
- 3. A method as set forth in claims 1 and 2. CHARAC-TERIZED in that the carbon-dioxide content of the inhaled gas mixture is adjusted in a range of from 0.0001 to 5%, using the exhaled carbon dioxide for the purpose.
- A method as set forth in claims 1-3, CHARACTER-IZED in that inhalation resistance is reduced by admitting an excess pressure.
- 5. A method as set forth in claims 1-4, CHARACTER-IZED in that conditions of carbon-dioxide absorption are improved by increasing the rate of gas mixture flow through a sorbent bed, and the carbondioxide content of the inhaled gas mixture is adjusted by bifurcating the exhaled gas mixture flow into two streams one of which is admitted to pass through the sorbent bed, while the other stream bypasses the latter.
- 6. An apparatus for forming a breathing gas mixture, comprising a device for producing a gas mixture incorporating a source (1) of compressed gas, said source communicating with a breathing mask (19) along pipings (6) and through a gas mixture composition regulator and a flow rate meter, a breathing bag (5), an inhalation valve (17), an exhalation valve (18) with the mask (19), an oxygen gas analyzer (14), and a control unit (8), CHARACTERIZED in that the device for producing a gas mixture appears as a number of containers (1) and (3) holding compressed oxygen and also at least one of the following gases: helium, and/or argon, and/or neon, and/or crypton, and/or xenon, and/or radon, and/or nitrogen, and/or nitrogen monoxide, and/or sulfur hexafluoride, or a mixture thereof, said containers communicating with the breathing bag (5) through

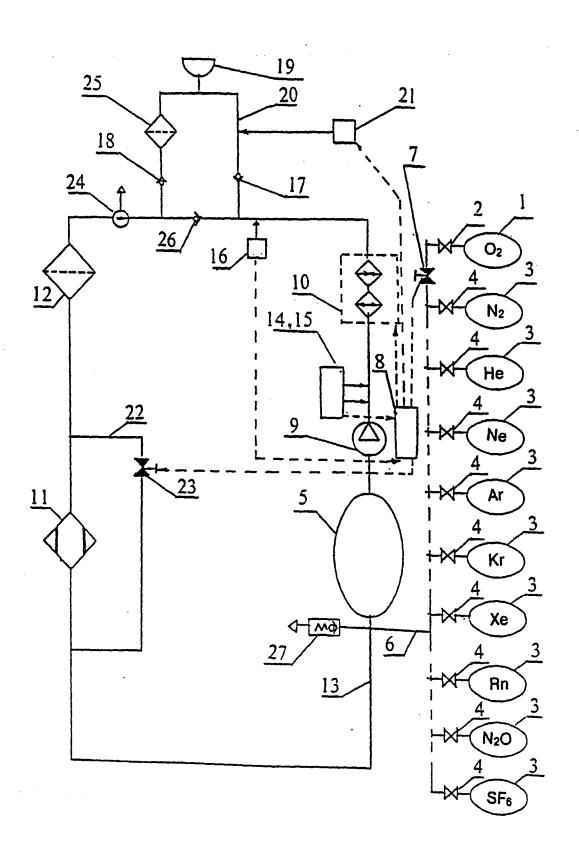
20

35

the pipings (6) provided with stop valves (2) and (4), at least the compressed oxygen container (1) being provided with a valve (7) remote-controlled from the control unit 8; the apparatus is provided with a circulation circuit built up by the breathing bag (5), a 5 gas flow inducer (9), a temperature controller (10), and at least one absorbent filter (11) and (12) of carbon dioxide, moisture, and harmful microimpurities exhaled by the patient into the apparatus, all these intercommunicating through pipings (13); 10 said circulation circuit communicates with the oxygen gas analyzer (14) and is additionally provided with a carbon-dioxide gas analyzer (15) and a temperature gauge (16), both of which establish, together with the oxygen analyzer (14), a measuring unit electrically connected to the control unit (8), and the mask (19) is connected, through pipings (20) with the valves (17) and (18), to said circulation circuit.

- 7. An apparatus as set forth in claim 6, CHARACTER-IZED in that an inhaler (21) is interposed between the inhalation valve (17) and the mask (19) and is connected to the piping (20) that feeds the gas mixture to the mask (19), said inhaler being adapted for feeding medicinal agents or moisture.
- 8. An apparatus as set forth in claims 6-7, CHARAC-TERIZED in that the carbon-dioxide absorbent filter is by-passed by an additional piping (22) provided with a controllable valve (23) for feeding part of a carbon dioxide-enriched gas flow directly to the breathing bag (5), thus by-passing the carbon-dioxide absorbent filter (11).
- An apparatus as set forth in claims 6-8, CHARAC-TERIZED in that the exhalation pipeline is provided with a gas flow switch (24) in order that the apparatus could operate on an open cycle.
- An apparatus as set forth in claims 6-9, CHARAC-TERIZED in that the carbon-dioxide absorbent filter (11) is revivifiable.
- An apparatus as set forth in claims 6-10, CHARAC-TERIZED in that the carbon-dioxide absorbent filter 11 is provided with a thermal reactivator.
- 12. An apparatus as set forth in claims 6-11, CHARAC-TERIZED in that it further comprises a device (25) for cleaning gases of microflora, said device being cut in the gas-mixture exhalation piping (20).
- 13. An apparatus as set forth in claims 6-12, CHARAC-TERIZED in that the circulation circuit comprises a non-return valve (26) which prevents reversal of the gas flow.

- 14. An apparatus as set forth in claims 6-13, CHARAC-TERIZED in that it further comprises a device for determining basal metabolism against patient's breathing.
- 15. An apparatus as set forth in claims 6-14, CHARAC-TERIZED in that the breathing bag (5) is provided with a relief valve (27) with an adjustable pressure setting.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/RU 96/00270

A. CLAS	SIFICATION OF SUBJECT MATTER		
IPC 6: A61M 16/12 According to International Patent Classification (IPC) or to both national classification and IPC			
B. FIELDS SEARCHED			
Minimum documentation searched (classification system followed by classification symbols)			
IPC 6: A61M 16/00, 16/10, 16/12			
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched			
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)			
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where app	Relevant to claim No.	
A	RU, C1, 2004261 (MURASHOV Mikhail Victorovich), 15 December 1993 (15.12.93)		1-5,6-15
A	SU, A1, 1304821 (VSESOJUZN) NAUCHNO-ISSLEDOVATELSKY INSTITUT MEDITSINSKOGO PRIBOROSTROENYA), 23 April 1987 (23.04.87)		1-5,6-15
A	SU, A, 1335294 (SPETSIALNOE KONSTRUKTORSKOE BJURO BIOFIZICHESKOI APPARATURY et al), 07 September 1987 (07.09.87)		1-5,6-15
٨	EP, A1, 0425092 (RESPIRONICS INC.), 02 May 1991 (02.05.91)		1-5,6-15
A	US, A, 5024219 (HENRY G. DIETZ) (18.06.91)	, 18 June 1991	1-5,6-15
Further documents are listed in the continuation of Box C. See patent family annex.			
• Special categories of cited documents: "T" later document published after the international filing date or priorit date and not in conflict with the application but cited to understan the principle or theory underlying the invention			
to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means		"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
		"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	
unit to an admittal and a size to the international filing date but later than		"&" document member of the same patent family	
Date of the actual completion of the international search Date of mailing of the international search report			earch report
10 December 1996 (10.12.96)		18 December 1996 (18.12.96)	
Name and mailing address of the ISA/		Authorized officer	
RU			
Facsimile No.		Telephone No.	